

### REMARKS

Claims 1-24 are currently pending. By this Amendment, claims 22 and 24 have been amended. Support for these amendments is present in the application as originally filed in at least paragraphs [00032], [0036], and FIGS. 1-3.

In view of the above amendments and below remarks it is believed that the pending claims are in a condition for allowance. Reconsideration of the pending claims and an indication of allowance is therefore respectfully requested.

#### Rejection of the Claims Under 35 U.S.C. § 103

##### The Combination of Desai and Epstein Do Not Make Claims 1 and 11 Obvious

Claims 1-3, 5-7, 9-18, and 20-21 stand rejected under 35 U.S.C. 103(a) as being obvious over Desai (U.S. Patent No. 6,461,296) in view of Epstein et al. (U.S. Publication No. 2003/0028172). Applicant respectfully traverses this rejection on the grounds that no *prima facie* case of obviousness has been shown. All of the limitations of independent claims 1 and 11 are not disclosed, taught, or suggested by the proposed combination.

The Office Action states that "Desai fails to disclose the use of a spring-loaded needle." Office Action, May 4, 2007, at 3. However, the Office Action further states that the use of spring-loaded needles "are old and well known as seen for example in Epstein et al." *Id.* "The advantage of a spring-loaded needle in the apparatus of Desai would be that it would allow for more efficient and effective actuation of the needle into tissue as taught by Epstein et al." *Id.* Epstein, however, does not teach, suggest, or disclose a spring loaded needle as claimed.

Claim 1 of the present application recites a method of delivering a denervating agent to a prostate gland" that includes "actuating a spring mechanism to cause the distal end of the spring loaded needle to spring bias into the prostate gland." Claim 11 recites a "system for delivering a denervating agent to a prostate gland" that includes a "spring loaded needle" and a "spring mechanism to bias the needle into the prostate gland upon actuation." Claims 1 and 11 therefore recite a spring loaded needle that uses the force of the spring to penetrate the tissue of the patient and to place the needle into the patient.

In contrast, Epstein utilizes a spring to stop the forward movement of a plunger which the user manually presses to force the needle into the patient. As shown in FIG. 2 and discussed in paragraph [0044]: "Upon depression, plunger 24 slides within plunger housing 31 until stopped by compression of spring 28 against depth stop 29. Spring 28 also provides a spring-loaded return feature when pressure on the plunger is released." Epstein, par. [0044]. The plunger for advancing the needle in Epstein "shown as needle actuator 22, functions similarly to [a] syringe." *Id.*

The proposed combination of Desai and Epstein, therefore, does not teach, suggest, or disclose all of the elements of independent claims 1 and 11. In addition, Applicants submit that claims 2-3, 5-7, 9-10, 12-18, and 20-21 are patentable over the cited references based upon at least their dependence from one of claims 1 and 11, each of which are believed to be in condition for allowance for at least the reasons stated above.

Moreover, claims 4, 8, and 19, which stand rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Epstein et al. as applied to claim 1, 7, and 11, and in further view of Henley et al. (U.S. Patent No. 6,477,410), are likewise patentable based upon their dependence from one of claims 1 and 11.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 1-21.

The Combination of Desai, Epstein, and Luther Do Not Make Claims 22 and 24 Obvious

Claims 22-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Desai in view of Epstein et al. and Luther et al. (U.S. Patent No. 7,037,294). Applicant respectfully traverses this rejection on the grounds that no *prima facie* case of obviousness was shown. Not all of the limitations of amended independent claims 22 and 24 are disclosed, taught, or suggested by the proposed combination.

Claim 22 includes limitations to a spring loaded needle and "means for spring-biasing the needle into the prostate gland" and claim 24 includes a limitation to "actuating a spring mechanism to cause the distal end of the needle to spring bias into the prostate gland at a first location." As explained above, the combination of Desai and Epstein does not teach, suggest, or disclose these limitations.

In addition, amended claim 22 recites "a spring loaded needle for insertion through the transurethral shaft and through a perineum of the patient in proximity to the prostate gland" and further including "means for spring-biasing the needle into the prostate gland such that a denervating agent can be delivered to the prostate gland through the lumen." The spring loaded needle is inserted through a shaft and can be rotated to deliver denervating agent to multiple prostate locations. Similarly, amended claim 24 recites "inserting a spring loaded needle through a perineum of the patient, the spring loaded needle extending through a shaft" and repositioning the spring loaded needle by "rotating the needle in the shaft by actuation of a wheel."

The Office Action cites to Luther as disclosing "a needle having a wheel which permits rotation of the needle to a desired orientation." Office Action, at 4. Luther, rather, teaches a hollow needle that can be "rotated by rotating the syringe barrel adapter." However, the needle is not intended to be rotated inside a shaft while inserted in the patient. Rather, "rotation of the hollow needle 120 while the hollow needle 120 is positioned within a patient's vasculature presents the risk of injuring the patient with the rotating beveled tip 122." Luther, col. 4, lines 13-17. When the needle is inserted into the patient Luther allows the "user to rotate the syringe barrel adapter 130 as required for convenience, without simultaneously rotating the hollow needle." Luther therefore does not teach, suggest, or disclose the ability to rotate the needle in a shaft while still inserted into the patient.

Claim 23 depends directly from claim 22 and incorporates all of the limitations of claim 2. Claim 23 is therefore allowable for at least those same reasons as presented above.

#### **Double Patenting**

Claims 1-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-12, 15-24 of copending U.S. Patent Application Serial No. 10/698,676. Applicants request that this rejection be held in abeyance until the claims have been indicated as allowable. At that time a terminal disclaimer will be submitted to overcome this rejection.

Application No.: 10/698,213  
Reply to Office Action of: May 4, 2007

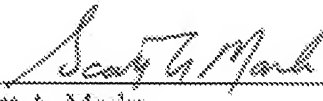
Conclusion

The Examiner is respectfully requested to contact the undersigned by telephone at 763.505.0409 or by e-mail at [scott.a.marks@medtronic.com](mailto:scott.a.marks@medtronic.com) with any questions or comments.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

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